Ballard Spahr LLP

1735 Market Street, 51st Floor
Philadelphia, PA 19103-7599
TEL 215.665.8500
FAX 215.864.8999
www.ballardspahr.com

Leslie E. John
Tel: 215.864.8212
Fax: 215.864.8999
john@ballardspahr.com

MEMO ENDORSED

April 14, 2022

Hon. Judge Kenneth M. Karas
United States District Court for S.D.N.Y.
300 Quarropas St., Chambers 533
White Plains, NY 10601-4150

Re: *PharmacyChecker.com, LLC v. National Association of Board of Pharmacy, et al.*, No. 7:19-cv-07577 (KMK): Pre-Motion Letter and Request for Conference on Defendants' *Daubert* Motion

Dear Judge Karas:

We represent the Partnership for Safe Medicines, Inc. Pursuant to your Individual Rules of Practice, we write on behalf of all Defendants to request a pre-motion conference prior to filing a *Daubert* motion to exclude the expert testimony of Benjamin England, Esq.

England is a lawyer and former FDA compliance officer who runs an FDA-focused law firm and consulting practice. *See* Ex. 1 England CV; Ex. 2 England Tr. at 12:2-8 (England holds licenses to practice law in Maryland and D.C.). In his Expert Report, England offers four opinions, the first three of which address the Food Drug and Cosmetics Act ("FDCA"), and related regulations and guidance documents. His first opinion is that "[d]rugs that comply with FDA's labeling and approval requirements can be and are legally imported . . . by individuals for their own personal use . . . ," and his second opinion is that drugs that have "labeling or packaging differences may be imported under FDA's drug labeling exemptions . . . [when imported] by individuals for their own personal use." Ex. 3 England Report at 5. His third opinion concerns FDA's Personal Importation Policy (PIP). England's fourth and ultimate opinion is that Plaintiff "does not buy, sell, distribute, dispense or process orders for drugs and its requirements for pharmacy participation in the accreditation program are clearly consistent with FDA's Personal Importation Policy and designed to ensure participating pharmacies conform to the FDA policy as mandated by Congress." *Id.*

The Court should exclude England's opinions for three reasons. First, England offers impermissible opinions of law, which not only usurp the role of the Court but also are unreliable as they are contrary to governing statutes and case law. Second, England's opinions are not reliable and lack fit to the issues of the case to the extent that he is offering opinions on FDA enforcement discretion. And finally, England's opinions will not assist the trier of fact because they are irrelevant to the critical issue of phase one discovery: whether "discovery supports Defendants' claim that the primary purpose [of Plaintiff's business] is to facilitate unlawful importation[.]" ECF No. 129 at 27-28 (internal citation omitted).

In order to admit England's expert testimony, the Court must conclude that England's testimony is based on reliable methodology and that it will "assist the trier of fact." *Nimely v. City of New York*, 414 F.3d 381, 397 (2d Cir. 2005). The Second Circuit "require[s] exclusion of expert testimony that expresses a legal conclusion." *Hygh v. Jacobs*, 961 F.2d 359, 363 (2d Cir. 1992).

The Court should exclude England's first three opinions about the FDCA and FDA regulations and guidance because they are impermissible legal conclusions. As a general rule, "an expert may not testify as to what the law is, because such testimony would impinge on the trial court's function." *In re Air Disaster at Lockerbie Scot.*, 37 F.3d 804, 826 (2d Cir. 1994). Courts in the Second Circuit consistently hold that "expert testimony is not admissible when it states an ultimate legal conclusion or communicates a legal standard to the jury." *Giles v. Rhodes*, No. 94-cv-6385, 2000 U.S. Dist. LEXIS 13980, at *53 (S.D.N.Y. Sept. 26, 2000). England testified that he did not "intend to give legal opinions in 1, 2, and 3." Ex. 2. at 36:6-12. Whether or not it was his intent, England repeatedly opines as to the lawfulness of personal importation under the FDCA. For example, in his first opinion, England opines that individuals can "legally" import for personal use "[d]rugs that comply with FDA's labeling and approval requirements." Ex. 3 at 5. The Court should exclude England's opinions about the FDCA and accompanying regulatory framework because his testimony inappropriately usurps the function of this Court.

The Court also should exclude England's first three opinions because they are incorrect statements of the law. In order to be admissible, expert testimony must be reliable. *Amorgianos v. Amtrak*, 303 F.3d 256, 266 (2d Cir. 2002). Inaccurate statements of law are inherently unreliable and thus inadmissible. *Loeffel Steel Prods., Inc. v. Delta Brands, Inc.*, 387 F. Supp. 2d 794, 806 (N.D. Ill. 2005). England's first three opinions about the legality of personal prescription drug importation rely upon 21 U.S.C. § 384(j) and the FDA's PIP guidance. Ex. 3 at 11. But, 21 U.S.C. § 384(l) provides that the section shall only become effective upon certification by the Secretary of Health and Human Services, and the Secretary has never made this certification as to Section 384(j). Ex. 2 at 178:8- 18. Section 384(j) has thus never become effective. *See id.* 184:12-186:9; Ex. 4 England-5. Although England expressed his belief that Section 384(j) is self-executing, Ex. 2 at 178:20-179:8, there is no legal support for this radical proposition. To the extent England relies upon the PIP to support his opinions of law, he admitted that "the guidance, yes, is considered to not be law." *Id.* at 54:5-13, 303:5-11. England even repeatedly disagreed with the law set forth in the Eight Circuit's decision *In re Canadian Import Antitrust Litigation*. *Compare* 470 F.3d 785, 790-791 (8th Cir. 2006), *with* Ex. 2 at 264:21-267:19. Not surprisingly, England did not review any case law in any Circuit when preparing his report. Ex. 2 at 107:5-110:4.

Seemingly to distance himself from the legal opinions contained in his report, England testified that his first three opinions "are designed to explain the context within which [FDA] compliance officers are operating[.]" *Id.* at 36:13-37:10. To the extent the Court gives this explanation credence, the Court should still exclude these opinions because the actions of

compliance officers in enforcing the law are irrelevant and constitute unreliable speculation. Whether or not FDA compliance officers choose to enforce the law or even the FDA's PIP guidance (which England admits does not have the force of law) does not speak to whether or not personal importation of prescription drugs is legal under the FDCA and is thus irrelevant to the critical issue of phase one discovery: whether Plaintiff's enterprise is geared toward facilitating illegal conduct. Allowing this testimony would only reward Plaintiff's strategy to confuse legality with FDA discretion.

Even if the Court is inclined to entertain testimony about FDA's enforcement of the PIP guidance as relevant to legality of personal importation, the Court should exclude England's opinions because they are unreliable speculation about individual discretionary decisions. England testified that, "on a case-by-case basis, there might be a discretionary decision that is made" by an individual FDA compliance officer in enforcing the PIP. *Id.* at 40:16-41:18; *see also id.* at 110:18-112:2 ("The compliance officers … what they're doing is – is always applying some level of discretion[.]"). He further testified that, "the compliance officers … when they are implementing this guidance, are primarily focusing on the health and safety component with respect to this product[.]" *Id.* at 200:9-201:6. But this opinion about what FDA compliance officers consider in enforcing the PIP guidance is merely based on his own experience in the 1990's as one compliance officer among hundreds. England admitted that "different compliance officers might weigh things differently" and he offers no reliable proof that his opinions reflect the majority view. *Id.* at 204:8-20. The Court should exclude this speculation as not based on any reliable methodology.

Finally, the Court should exclude England's fourth opinion about the design of Plaintiff's accreditation program as lacking in fit in that it is irrelevant to the critical issue of phase one discovery and as unreliable speculation. England's opinion that Plaintiff does not "buy, sell, distribute, dispense or process orders for drugs[,]" Ex. 3 at 5, does not bear on the question of whether Plaintiff's enterprise is "geared toward **facilitating** illegality" by providing consumers with links to online pharmacy websites to purchase drugs. ECF No. 220 at 2 (emphasis added). Similarly, England opines that Plaintiff's policies are "designed to ensure participating pharmacies conform to the FDA policy[,]" Ex. 3 at 5, but he is "not offering any opinion as to whether any PharmacyChecker-accredited pharmacy is complying with FDA's PIP[.]" Ex. 2 at 404:19-405:2. Besides being irrelevant to the question at hand, this opinion is inadmissible speculation. England testified that his fourth opinion is based solely upon his review of Plaintiff's website. *Id.* at 371:7-13. He did not interview or speak with any of Plaintiff's officers or employees. *Id.* at 124:9-14. England has no basis for testifying that Plaintiff's accreditation policy was designed to ensure compliance with FDA policy; in fact, [redacted]. Moreover, "[i]nferences about the intent or motive of parties … lie outside the bounds of expert testimony." *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004). Thus, the Court should exclude this unfounded opinion about Plaintiff's intent in designing its policies.

Very truly yours,

Leslie E. John

The Court will hold a pre-motion conference on both the proposed motion for summary judgment and the proposed *Daubert* motion on May 3, 2022 at 12PM, via teleconference.

The Clerk of Court is directed to terminate the pending motions at Dkt. Nos. 231, 233, 234, and 235.

SO ORDERED

KENNETH M. KARAS U.S.D.J.

4/25/22